NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Final draft guidance

Venetoclax with obinutuzumab for untreated chronic lymphocytic leukaemia

1 Recommendation

1.1 Venetoclax plus obinutuzumab can be used, within its marketing authorisation, as an option for untreated chronic lymphocytic leukaemia (CLL) in adults. It can only be used if the companies provide the technologies according to the commercial arrangements (see section 2).

What this means in practice

Venetoclax plus obinutuzumab must be funded in the NHS in England for the condition and population in the recommendation, if it is considered the most suitable treatment option. Venetoclax plus obinutuzumab must be funded in England within 90 days of final publication of this guidance.

There is enough evidence to show that venetoclax plus obinutuzumab provides benefits and value for money, so it can be used routinely across the NHS in this population.

Why the recommendation was made

This evaluation partially reviews the evidence for venetoclax plus obinutuzumab for untreated CLL. It reviews new evidence collected for the population in the managed access agreement for NICE technology appraisal guidance 663. This includes evidence from clinical trials and from people having the treatment through managed access in the Cancer Drugs Fund in England.

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Usual treatment for the population in the managed access agreement is venetoclax plus ibrutinib. Venetoclax plus obinutuzumab has not been directly compared in a clinical trial with venetoclax plus ibrutinib. But indirect comparisons suggest that they are likely to work as well as each other.

There are some uncertainties in the clinical evidence, which make the costeffectiveness evidence uncertain. But, the cost-effectiveness evidence suggests that venetoclax plus obinutuzumab has similar or lower costs than venetoclax plus ibrutinib.

In NICE technology appraisal guidance 663, NICE considered venetoclax plus obinutuzumab to be cost effective for the population outside the managed access agreement.

So, venetoclax plus obinutuzumab can be used for untreated CLL.

For all the evidence, see the <u>committee papers for this evaluation</u> and the <u>committee papers for NICE's technology appraisal guidance 663 on venetoclax with obinutuzumab for untreated chronic lymphocytic leukaemia</u>. For more information on streamlined evaluations, see NICE's manual on health technology evaluations.

2 Information about venetoclax plus obinutuzumab

Marketing authorisation indication

2.1 Venetoclax (Venclyxto, Abbvie) in combination with obinutuzumab is indicated for 'the treatment of adult patients with previously untreated chronic lymphocytic leukaemia'.

Dosage in the marketing authorisation

2.2 The dosage schedule is available in the <u>summary of product</u> characteristics for venetoclax.

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Price

- 2.3 A 112-pack of 100-mg venetoclax tablets costs £4,789.47 (excluding VAT; BNF online, accessed October 2025).
- 2.4 Abbvie has a commercial arrangement (simple discount patient access scheme). This makes venetoclax available to the NHS with a discount. The size of the discount is commercial in confidence. It is Abbvie's responsibility to let relevant NHS organisations know details of the discount.
- 2.4 The price of obinutuzumab is £3,312 per 1,000-mg vial (excluding VAT; BNF online, accessed October 2025).
- 2.5 Roche has a commercial arrangement (simple discount patient access scheme). This makes obinutuzumab available to the NHS with a discount. The size of the discount is commercial in confidence. It is Roche's responsibility to let relevant NHS organisations know details of the discount.

Carbon Reduction Plans

2.6 Information on the Carbon Reduction Plans for UK carbon emissions for Abbvie and Roche will be included here when guidance is published.

3 Implementation

- 3.1 Section 7 of the National Institute for Health and Care Excellence

 (Constitution and Functions) and the Health and Social Care Information

 Centre (Functions) Regulations 2013 requires integrated care boards,

 NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this evaluation within 90 days of its date of publication.
- 3.2 Chapter 2 of <u>Appraisal and funding of cancer drugs from July 2016</u> (including the new Cancer Drugs Fund) A new deal for patients,

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taxpayers and industry states that for those drugs with a draft recommendation for routine commissioning, interim funding will be available (from the overall Cancer Drugs Fund budget) from the point of marketing authorisation, or from release of positive draft guidance, whichever is later. Interim funding will end 90 days after positive final guidance is published (or 30 days in the case of drugs with an Early Access to Medicines Scheme designation or cost comparison evaluation), at which point funding will switch to routine commissioning budgets. The NHS England Cancer Drugs Fund list provides up-to-date information on all cancer treatments recommended by NICE since 2016. This includes whether they have received a marketing authorisation and been launched in the UK.

- 3.3 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal guidance recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 60 days of the first publication of the final draft guidance.
- 3.4 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has untreated CLL and the healthcare professional responsible for their care thinks that venetoclax plus obinutuzumab is the right treatment, it should be available for use, in line with NICE's recommendations.

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4 Evaluation committee members and NICE project team

Evaluation committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered as a streamlined evaluation by the lead team of committee C, which includes the chair and lead team.

Committee members are asked to declare any interests in the technology being evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

Chair

Richard Nicholas

Vice chair, technology appraisal committee C

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

Enna Christmas

Technical lead

Michelle Green

Technical adviser

Leena Issa

Project manager

Lorna Dunning

Associate director

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